

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Eric G. Lovett et al.) Examiner: Kennedy Schaetzle
Serial No.: 09/970,146) Group Art Unit: 3766
Filed: October 2, 2001) Docket: 279.262US1
For: MEDICAL DEVICE HAVING RHEOMETRIC MATERIALS AND
METHOD THEREFOR

REPLY BRIEF UNDER 37 C.F.R. § 41.41

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Commissioner for Patents
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Sir:

This Reply Brief is presented in response to the Examiner's Answer, dated July 13, 2006, which was sent in answer to Appellants' Appeal Brief, filed on April 17, 2006. Appellants' Appeal Brief was filed in response to the rejections of claims 1, 3-10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-69 of the above-identified application, as set forth in the Final Office Action dated October 5, 2005.

Please charge any required additional fees or credit overpayment to Deposit Account 19-0743.

1. REMARKS

The Examiner's Answer Brief, dated July 13, 2006, includes original grounds of rejection at pages 3-5 that correspond with the Final Office Action. Appellants respectfully maintain that the Appeal Brief, which is hereby incorporated by reference and reasserted in response, overcomes the original grounds of rejection found in the Final Office Action and resubmitted in the Answer Brief at pages 3-5. The original grounds of rejection are supplemented with new grounds of rejection in the Answer Brief at pages 5-13. Appellants traverse the new grounds of rejection in the section "Argument in further discussion of the rejections of claims 1, 3-10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-69." Pursuant to 37 CFR § 41.41(a)(2), Appellants respectfully submit the Reply Brief does not include any new or non-admitted amendment or any new or non-admitted affidavit or other evidence.

2. ARGUMENT IN FURTHER DISCUSSION OF THE REJECTIONS OF CLAIMS

1, 3-10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-69

a. Claims 1, 3-6 and 8 were improperly rejected under 35 USC § 102 as being unpatentable over Maseda (US Patent No. 6,514,237), hereinafter Maseda.

Appellants respectfully submit that the rejection of claims 1, 3-6 and 8 under 35 U.S.C. § 102 is improper. Reconsideration and allowance of claims 1, 3-6 and 8 are respectfully requested.

i. The Rejection of Claims 1, 3-6 and 8 Fails to Show the Allegedly Inherent Characteristic is Necessarily Present in Maseda.

Appellants respectfully submit the Answer Brief fails to support a finding of inherency to support the rejection of claims 1, 3-6 and 8, and therefore Maseda fails to anticipate at least claims 1, 3-6 and 8. Pursuant to *In re Rijckaert*, "The fact that a certain result or characteristic

may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). (Emphasis in the original). Further, according to *In re Robertson*, “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may *not be established by probabilities or possibilities*. The mere fact that a certain thing *may result* from a given set of circumstances is *not sufficient*.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (Emphasis added). Further still, pursuant to *Ex part Levy*, “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (Emphasis in original).

Moreover, the Answer Brief recites case law that bolsters Appellants’ position at page 5, last paragraph:

Regarding the rejection of claims 1 and 3-8, the examiner applies the principle of inherency. A claim feature is inherently met by a reference only if the feature is necessarily present in the reference. *Transclean Corp. v. Bridgewood Services Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002). It is not sufficient for inherency that a result *may* occur – it *must* invariably happen. *Scaltech Inc. v. Retec/Tetra. LLC*, 178 F.3d 1378, 1384 (Fed. Cir. 1999) (Emphasis ; *See also MEHL/Biophile International Corp., Milgram*, 192 F.3d 1362, 1365 (Fed. Cir. 1999).

The Answer Brief appears to impermissibly seize on probabilities and possibilities with respect to the Maseda reference without finding any teaching or providing any basis in fact and/or technical reasoning to reasonably support the determination that at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1, *necessarily* flows from the teachings of the cited reference. Claims 3-6 and 8 depend from claim 1, and thereby include all of its limitations. For example, the Answer Brief states at page 6, first paragraph, “The examiner

again refers the appellants to col. 5, lines 1-23 which explicitly refers to the use of ion-exchange polymer-noble metal composites (IPMC) including dendritic-type deposited electrodes of platinum coupled to the device body.” Appellants traverse this statement in so far as it fails to properly characterize the recitations of Maseda. Maseda states at column 5, lines 1-19:

Ion-exchange polymer-noble metal composites are manufactured utilizing a chemical process in which a noble metal is deposited within the molecular network of the base ionic polymer. Metal ions, for example, platinum are dispersed throughout the hydrophilic regions of the polymer and subsequently chemically reduced to the corresponding metal atoms. This process results in the formation of dendritic-type electrodes. When an external voltage of approximately 2 volts or higher is applied to an ion-exchange polymer-noble metal composite film, it bends toward the anode. An increase in the applied voltage, up to a predetermined limit, causes a larger bending displacement. When the polarity of the voltage is changed, the film undergoes a swinging movement. The displacement of the film not only depends on the magnitude of the applied voltage, but also on the frequency of the applied voltage. Lower frequencies lead to higher displacements. Accordingly, the movement of the film or strip may be fully controllable by controlling the applied voltage.

Maseda, column 5, lines 1-19. Appellants respectfully submit the preceding quotation is the only teaching for an electrode in Maseda and does not appear to show at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1, is necessarily present in the cited reference. Moreover, Appellants traverse the Answer Brief statement at page 8, first paragraph:

[T]he word *electrode* by its very definition pertains to a conductor used to establish electrical contact with a nonmetallic part of a circuit. The electrode is thus configured to establish electrical contact to and from tissue (the tissue being a nonmetallic part of the circuit). There is no reason to believe . . . that Maseda intended to give the term any special meaning that would preclude application of this common definition.

Appellants, respectfully traverse the statement as the Answer Brief appears to develop its own definition for the electrode of Maseda and thereafter provide a conclusory and unsupported discussion as to its *supposed* function, while ignoring the previously described teaching for the electrode found in Maseda at column 5, lines 1-19.

Further, the Answer Brief goes on to state at page 6, last paragraph to page 7, first paragraph, “In fact, in order for the electrode assembly of Maseda to work, it *must* inherently be

capable of receiving and transmitting electrical signals in order for the requisite electrical field as discussed in col. 4, lines 55-57 and col. 5, lines 8-19 to be created and concomitantly allow the rheometric material sandwiched between the anode and cathode to cause the assembly to bend and flex.” Based on this quotation, and other similar quotations throughout the Answer Brief, Appellants respectfully submit the Answer Brief confuses the issue of what must be shown to establish the missing characteristic is inherently present in the cited reference. As stated above, pursuant to *In re Robertson and Transclean Corp. v. Bridgewood Services Inc.*, it must be shown that the missing descriptive matter is *necessarily present* in the thing described in the reference. Appellants are not arguing, for instance, that Maseda fails to teach an electrode. Instead, Appellants can not find that Maseda shows at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1, is necessarily present in the cited reference.

The Answer Brief attempts, but fails to show a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic recited in claim 1 *necessarily* flows from the teachings of the cited reference, as required by *Ex parte Levy*. For instance, the Answer Brief states at page, 7 first paragraph, “Maseda further teaches that such materials in strip or strand form can be attached to the *outer* tubular body 114 and can be bonded to the *surface* of the outer tubular body (col. 5, lines 20-23 and 56-64) thus placing the material in a position to contact tissue.” (Emphasis in the original). Additionally, the Answer Brief states at page 7, last paragraph, “The platinum electrode of Maseda can be attached to the outer tubular body 114 enabling it to come into contact with tissue or conductive bodily fluids. The platinum electrode of Maseda is thus capable of transmitting and receiving electrical signals to and from the tissue.” However, the actual passages of Maseda state at column 5, lines 20-65, “strips or strands of ion-exchange-polymer-noble metal composites may be integrated into one or more sections of a flexible medical probe device . . . a composite strand is attached to the outer tubular body 114 . . . When no voltage is applied across the composite strand 306, the composite strand is pliable and soft.” Appellants respectfully submit that the above recited passages relied on by the Answer Brief fail to show at least one electrode coupled with the device body, where the at

least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1, is necessarily present in the cited reference. At the very most, the Maseda passages amount to a possibility or a probability of having all of the elements of claim 1, and therefore fall short of having the elements of claim 1 necessarily present. For example, in a similar manner to Maseda, voltages are routinely applied across electrodes to provide electricity to appliances without being able to also transmit and receive electrical signals to and from tissue, such is the case with an insulated cord plugged between a wall outlet and an appliance. Because Maseda appears to only describe using electrodes to make the strands 306 rigid, Appellants respectfully submit that at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1, is not necessarily present in the cited reference.

Additionally, Appellants traverse the Answer Brief statement at page 8, last paragraph, “By any measure, the examiner has clearly established that a preponderance of the evidence supports the inherency basis of his rejection . . . [I]t is thus submitted that a *prima facie* case of inherency has been established and the burden is on the appellants to prove otherwise.” Appellants respectfully submit that the Answer Brief has failed to establish a case of inherency, as described above. Specifically, the Answer Brief fails to show the missing descriptive matter is *necessarily present* in the cited reference, as required by *In re Robertson* and *Transclean Corp. v. Bridgewood Services Inc.* Further, Appellants respectfully submit the discussion above proves the allegedly inherent characteristic is not *necessarily present* in Maseda, as required by *In re Robertson* and *Transclean Corp. v. Bridgewood Services Inc.*

Therefore, because Maseda fails to identically show all of the claimed limitations of claim 1, inherently or otherwise, Appellants respectfully submit the cited reference fails to anticipate claims 1, 3-6 and 8.

ii. The Rejections of Claims 1, 3-6 and 8 Fail to Provide a Proper Case of Anticipation Because the Final Office Action and the Answer Brief Fail to Give Patentable Weight to Functional Limitations.

The rejections of claims 1, 3-6 and 8 fail to state a proper case of anticipation because the Final Office Action fails to consider functional limitations in the claims, as required by *In re Swinehart and Lewmar Marine, Inc. v. Barient, Inc.* Pursuant to *In re Swinehart*, “[a] functional limitation must be evaluated and considered, just like any other limitation of the claim . . . A functional limitation is often used in association with an element . . . to define a particular capability or purpose that is served by the recited element.” See *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971); *In re Caldwell*, 138 USPQ 243 (CCPA 1963); *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987) (“so that” functional clause of claim renders reference non-anticipating). Appellants asserted this position in the Appeal, and reassert it here again based upon statements in the Answer Brief at page 7, last paragraph (emphasis in the original):

The examiner further cannot find in the claim where it is stated that the electrode *must* perform transmission and reception of electrical signals to and from tissue. The examiner for example, cannot find any structure in the claim for generating such signals and sensing such signals. The electrode only need be *capable* of such action.

Appellants traverse this statement. Further, based upon this statement and nearly identical statements made in the Final Office Action at page 5, first paragraph, Appellants respectfully assert the Final Office Action and Answer Brief refuse to give patentable weight to a functional limitation, for instance, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. Pursuant to *In re Swinehart*, any functional limitation may not be ignored and must be considered just like any other limitation of the claim. Claims 3-6 and 8 depend from claim 1 and thereby include all of its limitations. As stated above, Appellants can not find in Maseda, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1 and incorporated in dependent claims 3-6 and 8. Reconsideration and allowance of claims 1, 3-6 and 8 are respectfully requested.

b. Claim 7 was improperly rejected under 35 USC § 102 as being unpatentable over Maseda.

Appellants respectfully submit that the rejection of claim 7 under 35 U.S.C. § 102 is improper. Reconsideration and allowance of claim 7 are respectfully requested.

i. The Rejection of Claim 7 Fails to Show the Allegedly Inherent Characteristic is Necessarily Present in Maseda.

As previously stated in the Appeal Brief, Appellants submitted the Final Office Action failed to state a proper case of anticipation because Maseda does not identically show each of the claimed elements, as required by *In re Bond*. According to the Answer Brief at page 5, last paragraph, “[r]egarding the rejection of claims 1 and 3-8, the examiner applies the principle of inherency,” Appellants submit the Answer Brief now attempts to apply inherency to supplement the original grounds of rejection. Appellants respectfully submit the Answer Brief fails to support a finding of inherency to support the rejection of claim 7, and therefore Maseda fails to anticipate at least claim 7.

As with claims 1, 3-6 and 8 as discussed above, the Answer Brief appears to impermissibly seize on probabilities and possibilities with respect to the Maseda reference without finding any teaching or providing any sufficient basis in fact and/or technical reasoning to reasonably support the determination that the device body comprising an elongate lead body configured to be coupled with a pulse generator, as recited in claim 7, *necessarily* flows from the teachings of the cited reference. For example, the Answer Brief states at page 9, second paragraph (Emphasis in the original):

In order for the elongated body of Maseda to apply the requisite electrical control signals from control module 300 to the rheometric material via electrical conduit 302 (see Fig. 3), artisans of ordinary competence would understand that the elongated lead body of Maseda absolutely, positively *must* be configured to be coupled with an electrical signal generator . . . (b) a lead body configured to be coupled to a source of electrical energy is inherently capable of being connected to a pulse generator.

Appellants traverse this statement in so far as it fails to properly characterize the recitations of Maseda. According to the Answer Brief rationale, the controllable intralumen device of Maseda is couplable with a control module 300 that includes almost any source of electrical energy, including for instance a pulse generator. The Answer Brief appears to further argue this overbroad definition at page 10, first paragraph:

The examiner . . . will further argue that the signal generator of Maseda can reasonably be considered a pulse generator. Maseda discloses that when an electric voltage is applied to the rheometric material, the material will bend or twist, and when no voltage signal is applied the material will relax . . . By turning on and off this control voltage in order to selectively bend and relax the tip . . . one is by default pulsing the control signal on and off. The control module 300 is thus a pulse generator.”

However, Maseda appears to provide a narrower definition of what the controllable intralumen device is configured to couple with. For example, Maseda states at column 5, lines 41-43, “The control module 300 preferably comprises a power supply capable of supplying both DC voltage/current and AC voltage/current at various frequencies.” As previously stated in the Appeal Brief and resubmitted here, the preceding quotation from Maseda and the statements relied on by the Answer Brief do not appear to teach the *identical invention in as complete detail* as is contained in claim 7, and required by *In re Bond* and *Richardson v. Suzuki Motor Co.* Appellants respectfully submit the Answer Brief now attempts to impermissibly broaden the teachings of Maseda under the guise of inherency without providing any teaching from the cited reference or legally sufficient technical reasoning that the device body comprising an elongate lead body configured to be coupled with a pulse generator, as recited in claim 7, is *necessarily present* in the cited reference. At most, the Answer Brief attempts to argue that the possibility or probability that Maseda teaches a device body comprising an elongate lead body configured to be coupled with a pulse generator, as recited in claim 7, is sufficient to support a position of inherency. However, according to *In re Robertson*, inherency may not be established by *probabilities or possibilities*.

Appellants respectfully submit that the Answer Brief has failed to establish a case of

inherency, as described above. Specifically, the Answer Brief fails to show the missing descriptive matter is *necessarily present* in the cited reference, as required by *In re Robertson* and *Transclean Corp. v. Bridgewood Services Inc.* Further, Appellants respectfully submit the discussion above proves the allegedly inherent characteristic is not *necessarily present* in Maseda, as required by *In re Robertson* and *Transclean Corp. v. Bridgewood Services Inc.*

Moreover, because claim 7 is a dependent claim and thereby must be read in combination with independent claim 1, claim 7 necessarily includes the elements of claim 1, and requires at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue *in combination with* an elongate body configured to be coupled with a pulse generator. Appellants can not find teaching in Maseda showing such elements and respectfully submit the Answer Brief fails to make a proper case of anticipation.

Because Maseda fails to identically show all of the claimed limitations of claim 7, inherently or otherwise, Appellants respectfully submit the cited reference fails to anticipate claim 7.

ii. The Rejection of Claim 7 Fails to Provide a Proper Case of Anticipation
Because the Final Office Action and Answer Brief Fail to Give Patentable Weight to Functional Limitations.

As previously discussed above, *In re Swinehart* requires that a functional limitation must be evaluated and considered, just like any other limitation of the claim. In contravention of established case law including *In re Swinehart*, the Answer Brief attempts to seize upon an unknown and legally unsupported standard for patentability in requiring “structural differences.” For instance, the Answer Brief states at page 9, last paragraph, “[t]he fact that the appellants refer to the generator as a *pulse* generator makes no structural difference whatsoever because: (a) the appellants’ claim does not set forth a pulse generator . . . It is unclear, for example, what structural difference it makes that the intended generator is a pulse generator.” (Emphasis in the

original). Appellants respectfully submit that the Answer Brief fails to give patentable weight to the device body comprising an elongate lead body configured to be coupled with a pulse generator, as recited in claim 7. Additionally, Appellants respectfully traverse the Answer Brief statement at page 9, last paragraph, “It is unclear why one would be prevented from connecting a pulse generator to the conduit access port 304 . . . A wire is capable of transmitting whatever form of electrical signal so happens to be connected to it.” Appellants submit the Answer Brief appears to narrowly refer to modes of connection with a power supply as opposed to the device body comprising an elongate lead body being configured to be coupled with a pulse generator, as recited in claim 7. For example, as previously stated, because claim 7 depends from claim 1, it necessarily incorporates all of the recitations of claim 1. Accordingly, claim 7 recites a device body comprising an elongate lead body being configured to be coupled with a pulse generator *in combination with*, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. Appellants can not find in Maseda such a device body configured to be coupled with a pulse generator. Reconsideration and allowance of claim 7 are respectfully requested.

The Final Office Action and the Answer Brief fail to provide a proper case of anticipation because Maseda does not show the identical invention in as complete detail as is contained in claim 7. Reconsideration and allowance of claim 7 are respectfully requested.

c. Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 were improperly rejected under 35 USC § 103 as being unpatentable over Lieber et al. (U.S. 4,329,993), hereinafter Lieber, in view of Maseda.

Appellants respectfully submit that the rejections of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 under 35 USC § 103 are improper. Reconsideration and allowance of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 are respectfully requested.

i. The Rejections of Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68

Fail to Maintain a *Prima Facie* Case of Obviousness Because Combining Maseda and Lieber In the Proposed Manner Would Impermissibly Change the Principle of Operation of Lieber, and There is No Objective Supported Suggestion to Combine Maseda and Lieber In the Manner Proposed.

As stated in the Appeal Brief, the rejections of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 fail to maintain a *prima facie* case of obviousness because, among other reasons, combining Maseda with Lieber in the proposed manner would change the principle of operation of Lieber. According to *In re Ratti*, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810 (CCPA 1959); MPEP § 2143.01. Appellants respectfully submit Lieber states at column 3, lines 52-64:

In use, the soft, pliable catheter body . . . is advanced, with the balloon in deflated or only partially inflated condition, into the right atrium 12. The balloon is then inflated to its maximum recommended capacity and the flow of blood through the heart rapidly propels the inflated balloon-tipped catheter from the right atrium into the pulmonary artery 18 (FIG. 1). It will be observed that when the catheter is so positioned, balloon 26 has advanced through the pulmonary artery into . . . the pulmonary capillary position.
In contrast, Maseda recites in the abstract, for example, “an intralumen medical device which incorporates electroactive polymer actuators into various sections of flexible medical probes results in a device capable of precisely navigating through tortuous passageways.” Appellants submitted in the Appeal Brief and resubmit in here that by exchanging the inflated balloon mechanism of Lieber with the electroactive polymer actuators of Maseda the principle of operation for navigating the vasculature of Lieber is impermissibly changed, and according to *In re Ratti*, the proposed combination is thereby insufficient to render claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 *prima facie* obvious.

Further, Appellants respectfully traverse the Answer Brief statement at page 11, last paragraph, “The examiner knows of no valid reason why skilled artisans would consider the two systems to be mutually exclusive.” Appellants are unaware of such a rule being provided in the

holding of *In re Ratti*. Instead the rule of *In re Ratti* states that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. By exchanging the inflated balloon mechanism of Lieber with the electroactive polymer actuators of Maseda the principle of operation for navigating the vasculature of Lieber is impermissibly changed, and the proposed combination is thereby insufficient to render claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 *prima facie* obvious.

Moreover, the Answer Brief goes on to state at page 11, last paragraph to page 12, first paragraph:

Precise medical devices as well as common every-day items frequently incorporate both course adjustment and fine-tuning systems to no detriment (e.g., stereo tuners, microscopes, televisions, etc., all allow for course and fine-tune adjustment to effectively zero in on the correct setting or equipment placement). It is unclear why a medical device, where precise placement of sensor structure is often crucial to proper diagnosis and treatment, would be any different. The passive balloon placement system of Lieber et al., for example, may not allow proper placement of the distal sensor if the soft, pliable device body encounters an arterial blockage or is hampered in reaching its final intended position.

The Answer Brief further states at page 11, last paragraph:

Since the device of Lieber et al. is intended for placement within the pulmonary arteries of patients suffering from cardiovascular and pulmonary diseases in an effort to properly diagnose and quantify their condition, it would not be unreasonable to expect to find stenotic lesions and other health-affecting blockages of the pulmonary artery. Anyone of ordinary skill in the art would have readily seen the provision of a navigational system to enable one to selectively and precisely steer a soft, pliable catheter body such as disclosed by Lieber et al, around a blockage in order to enable placement of the catheter body in the proper location, to be a decided advantage.

Appellants traverse these statements in so far as the Answer Brief impermissibly attempts to manufacture a subjective suggestion to have dual systems in a single device without providing any objective support in the references as to why a second system for navigation is needed. The Answer Brief appears to develop its own rationale as to the *supposed* shortcomings of Lieber (e.g., that by itself the system of Lieber is not capable of proper placement) and then use that

manufactured rationale as groundless support for combination of the inflated balloon mechanism of Lieber with the electroactive polymer actuators of Maseda as a sort of “fine-tuning” system. In effect, the Answer Brief solves its own subjectively designed problem in order to manufacture a suggestion to combine the references. However, pursuant to *In re Mills*, the mere fact that references *can* be combined does not render the resultant combination obvious unless prior art also suggests (i.e. a prior art supported objective suggestion) the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

Further, according to *In re Fine*, “the rationale to modify or combine the prior art . . . may be expressly or impliedly contained in the prior art or it may be *reasoned* from knowledge generally available to one of ordinary skill in the art, established scientific principles or legal precedent.” (Emphasis added). *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). However, the recent holding of *In re Sang Su Lee* clarifies that the “factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.” *In re Sang Su Lee*, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002). As stated above, the Answer Brief impermissibly solves its own subjectively designed problem in order to manufacture a suggestion to combine the references in the proposed manner. The Answer Brief thereby fails to supply a sufficient objectively supported motivation to combine Maseda with Lieber in the manner proposed, as required by *In re Sang Su Lee*. The failure of the Answer Brief to supply such a motivation is further compounded because combining Maseda with Lieber would impermissibly change the principle of operation for navigating the vasculature of Lieber, in contravention of *In re Ratti*. The Final Office Action and Answer Brief thereby fail to maintain a *prima facie* case of obviousness. Reconsideration and allowance of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 are respectfully requested.

ii. The Rejections of Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 Fail to State a *Prima Facie* Case of Obviousness Because The Final Office Action Does Not Consider the Claims as a Whole.

Further still, the rejections of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 fail because the rejections do not consider the claims as a whole. As stated in the Appeal Brief and resubmitted here, the Final Office Action and Answer Brief seize upon the differences of the claims and argue the differences would be obvious instead of considering the claims as a whole, in contravention of *Interconnect Planning Corp. v. Feil*. The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). Further, in determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences *themselves* would have been obvious, but whether the claimed invention *as a whole* would have been obvious. (Emphasis in original). *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985); MPEP § 2141.02. The Answer Brief states at page 13, last paragraph, “The examiner clearly has considered the claims as a whole, has formulated a valid, reasonable *prima facie* case of obviousness based on explicit teachings in the prior art.” Based on the failure of the Final Office Action and Answer Brief to maintain a *prima facie* case of obviousness, as described above, Appellants respectfully traverse this statement. Instead, the Final Office Action and the Answer Brief attempt to impermissibly manufacture a motivation to combine Maseda with Lieber in the manner proposed as discussed above. Based on the failure to maintain a *prima facie* case of obviousness, Appellants can only assume the Final Office Action and the Answer Brief merely state the differences of the claims with respect to the prior art are obvious without focusing on the claims as a whole. For instance, the Final Office Action states at page 3, last paragraph:

“Lieber et al. disclose a medical device comprising an elongate device body and at least one electrode 35 coupled thereto for stimulating and sensing. Lieber et al., however, do not disclose the use of an assembly coupled with the device body including a rheometric material that contracts and/or stiffens when electrical current is applied thereto. Maseda, however, teach that the use of such an assembly on a wide range of medical devices including the type disclosed by Lieber et al. is advantageous.”

Appellants submitted in the Appeal Brief and resubmit here in response to the Answer Brief that the Final Office Action and Answer Brief state the differences of the claims with respect to the base reference, Lieber, are obvious and then pick and choose at least one missing element from Maseda without focusing on the claims as a whole, as required by *Stratoflex, Inc. v. Aeroquip Corp.*

Moreover, the Answer Brief states at page 13, last paragraph, “It is unclear what point the appellants are attempting to make by simply highlighting the phrase, ‘in combination with all of the elements.’” Appellants respectfully submit that the statements referred to by the Answer Brief and provided at page 16 of the Appeal Brief respond to the Final Office Action statement at page 3, last paragraph, provided in the preceding paragraph. By stating, for instance, “claim 9 recites that the medical device includes, *in combination with all of the elements of claim 9*, at least one assembly including a rheometric material, the rheometric material contracts and/or stiffens when current is applied thereto,” Appellants wished to highlight for the Appeals Board that because an objective supported motivation to combine had not been provided, that the Final Office Action (and now the Appeal Brief as well) failed to properly consider the claims as a whole.

Additionally, because a *prima facie* case of obviousness has not been provided in the Final Office Action or in the Answer Brief, Appellants submit the Final Office Action and Answer Brief impermissibly attempt to use Appellants’ disclosure as a template and perform improper hindsight reconstruction. Pursuant to *In re Gorman*, the Examiner cannot use the Appellants’s structure as a “template” and simply select elements from the references to reconstruct the claimed invention. *In re Gorman*, 933 F.2d 982, 987, (Fed. Cir. 1991). Appellants submit the Answer Brief and the Final Office Action simply pick and choose elements from the cited references to combine to meet each of the recitations of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68. The rejections of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 fail because the Final Office Action and the Answer Brief fail to properly consider the claims as a whole. Moreover, Appellants respectfully traverse the Answer Brief

REPLY BRIEF UNDER 37 C.F.R. § 41.41

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statement at page 12, last paragraph, “The examiner argues that the appellants’ attorney is confusing the entire basis of the § 103 rejection, thus rendering this argument totally moot.” Appellants respectfully submit the lengthy discussion provided above fully addresses the failure of the Final Office Action, and now the Answer Brief, to provide a *prima facie* case of obviousness. Reconsideration and allowance of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 are respectfully requested.

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3. SUMMARY AND REMARKS CONCERNING THE RESPONSE TO ARGUMENTS

The Final Office Action and the Answer Brief fail to establish legally sufficient cases of anticipation or obviousness and Appellants respectfully traverse on several grounds as described above and in the Appeal Brief.

In light of the above, Appellants submit that when the cited references are properly considered for only what they teach or suggest, and when the actual claim language is examined without hindsight reconstruction, the pending claims are patentable over the cited art. Reconsideration and allowance are respectfully requested.

Respectfully submitted,

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By their Representatives,

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9/3/06

By

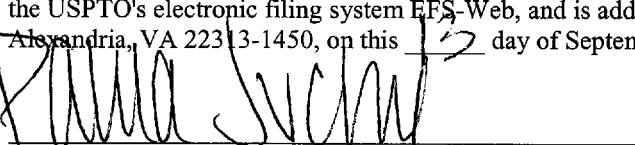


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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12 day of September, 2006.

Name



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